



American Bakers Association

Serving the Baking Industry Since 1897

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September 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 98P-0683; Food Labeling: Health Claims; Soy Protein
and Coronary Heart Disease; 64 Fed. Reg. 162 (August 23, 1999)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of approximately 300 bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. ABA members produce a wide variety of baked goods, including low fat breads, rolls and muffins that make a significant nutritional contribution to the diets of many consumers and that currently or potentially may include soy protein. ABA thus has a critical interest in this reproposal on soy protein/coronary heart disease ("soy/CHD") health claim with regards to the specific analytical methodology to measure soy protein in baked goods and access to supporting documentation.

Analytical Methodology

As ABA stated in its previous January comments, our industry adamantly disagreed with FDA's choice of Association of Official Analytical Chemists International (AOAC) official method of analysis No. 988.10 as the test methodology for evaluating compliance for soy protein in baked goods. ABA appreciates the fact that FDA acknowledges, through the objections raised by ABA and other organizations, that this methodology is not appropriate. At the same time, ABA notes that the most recent proposal is also unacceptable for bakery products because it is recipe-based on a checks and balance system, not on an AOAC/AACC-approved scientifically accurate methodology, which is needed for any health claim.

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Given the methodological complexity of the issues presented, and the short time frame until completion of the rulemaking, ABA agrees that FDA should proceed to finalize the rulemaking at this time. It should be noted that baked goods contain a variety of protein sources including wheat flour, gluten, non dry fat milk, milk replacer, yeast and other grains. A soy based milk replacer could even be used to supplement the quantity of soy protein. While FDA acknowledges the complicated nature of the analytical problem in calculating the total protein and assigning specific parts of that total protein to specific sources, ABA believes a recipe-based system would be so complex as to be extremely burdensome on both the FDA inspector and the baker. Additional training may be needed by FDA inspectors to determine these calculations.

Records Access

ABA strongly disagrees with FDA's argument, however, that it should have access to records of manufacturers of such bakery products, or that such bakers should be deprived of their constitutional right to make truthful and non-misleading health claims unless they relinquish the rights over records provided by section 704 of the Food Drug and Cosmetic Act. Section 704 explicitly limits FDA records access for foods to product labeling. Formulations are not included, as FDA's own inspection policy recognizes (FDA Investigations Operations Manual, Chapter 5). Additionally, nothing in the NLEA health claim provisions expands FDA's authority over records.

ABA recognizes that, where questions are raised with respect to the basis for a soy protein health claim, a baker may find it necessary to share analytical data results information with the agency voluntarily in order to demonstrate that the claim is substantiated. FDA has no authority; however, to demand such records access.

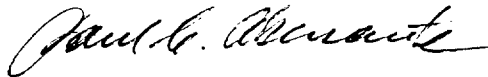
If FDA proceeds to demand routine access to records to verify the amount of soy protein in foods whose labeling bears a soy protein health claim, or authorize use of the claim only on foods whose sole source of protein is from soy, it would clearly provide an unfair market advantage to one-source products and would defeat the purpose of the original proposal, which was to encourage increased soy consumption through mainstream food products.

The agency's proposal for one-source foods would dramatically limit foods qualifying for the claim. Foods that would qualify, such as tofu, soy burgers and soymilk, are not commonly accepted in significant amounts by the consuming public, and thus, are unlikely to contribute significant cardio-vascular benefits in the absence of consumption of the more commonly consumed products that could potentially include soy protein.

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ABA appreciates this additional opportunity to comment on this proposal which is of interest to the wholesale baking industry. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898—1164. We would be pleased to provide any additional technical information that would be of assistance to the agency in establishing more appropriate nutritional criteria for the soy/CHD claim.

Respectfully submitted,

A handwritten signature in cursive script, reading "Paul C. Abenante".

Paul C. Abenante
President & CEO
American Bakers Association